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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application No. : 10/074,744
Applicant : Padidam
Filed : February 13, 2002
Art Unit : 1636
Examiner : Terry Alan McKelvey
Docket No. : A01183-US
Customer No. : 37978

Mail Stop Patent Application
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Reply to Restriction Requirement under 37 C.F.R. § 1.143

Dear Sir:

In reply to the Restriction Requirement, mailed October 8, 2003, Applicants provisionally elect Group IV, claims 1-10 drawn to a method to reduce transcriptional interference using a spacer polynucleotide comprising SEQ ID NO: 4, with traverse. Applicants respectfully request reconsideration of the Requirement for Restriction, or in the alternative, modification of the Restriction Requirement to allow prosecution of more than one group of claims designated by the Examiner in the present Application, for the reasons provided as follows.

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REMARKS

Claims 1-14 are pending in this application. The Examiner contends that this Application contains the following inventions or groups of inventions which allegedly are unrelated:

Group I, claims 1-10, drawn to method to reduce transcriptional interference, using a spacer polynucleotide comprising SEQ ID NO: 1;

Group II, claims 1-10, drawn to method to reduce transcriptional interference, using a spacer polynucleotide comprising SEQ ID NO: 2;

Group III, claims 1-10, drawn to method to reduce transcriptional interference, using a spacer polynucleotide comprising SEQ ID NO: 3;

Group IV, claims 1-10, drawn to method to reduce transcriptional interference, using a spacer polynucleotide comprising SEQ ID NO: 4; and

Group V, claims 11-14, drawn to cell and non-human organism.

The examiner suggested that the methods of Groups I-IV are drawn to the use of different nucleotide sequences which appear to be independent and distinct sequences and thus the methods that are drawn to the use of the independent and distinct sequences are independent and distinct.

In reply, and solely to be responsive to the Examiner's requirement, Applicants provisionally elect Group IV, claims 1-10, drawn to method to reduce transcriptional interference, using a spacer polynucleotide comprising SEQ ID NO: 4, with traverse.

Under 35 U.S.C. § 121, restriction may be required if "two or more independent and distinct inventions are claimed in one application." According to the interpretation provided in MPEP § 802.01, the term "independent" means that "there is no disclosed relationship between the two or more subjects disclosed, that is, they are unconnected in design, operation or effect...." The term "distinct" is defined in MPEP § 801.02 as meaning that "two or more subjects as disclosed are related... but are capable of separate manufacture, use or sale as claimed, and ARE PATENTABLE (novel and unobvious) OVER EACH OTHER..." (emphasis in original). However, even with patentably distinct inventions, restriction is not required unless one of the following reasons appear (MPEP 808.02):

1. Separate classification;
2. Separate status in the art; or
3. Different field of search.

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The above-cited language of 35 U.S.C. § 121 is clear in that the requirement to restrict an application to one of the inventions disclosed therein is proper only if the disclosed inventions are both independent and distinct. While Applicants take no position on the patentable distinctness of Groups I-V, Applicants submit that the claims of Groups I-V are not independent and are so linked as to form a single general inventive concept. The lengthy explanation provided in MPEP § 802.01 of why restriction can be properly required among independent or distinct inventions is in contradiction to the plain language of the statute and the related rules (37 C.F.R. § 1.142). Accordingly, a restriction based upon the alternative use of these terms is questionable.

However, even if one accepts the MPEP's interpretation of 35 U.S.C. § 121, the mere existence of two or more independent or distinct inventions in one application is not sufficient to justify a restriction requirement.

According to the guidelines in MPEP § 803, if the search and examination of an entire application can be made without serious burden, the examiner must examine it on the merits, even though it includes claims to distinct or independent inventions.

Examination Of Claims 1-14 Does Not Present Undue Burden On The Examiner

Applicants respectfully submit that prosecution of the claims of Groups I-V designated by the Examiner in the present Application is appropriate. Under Patent Office examining procedures, "[i]f the search and examination of an entire application can be made without serious burden, the Examiner must examine it on the merits, even though it includes claims to distinct or independent inventions" (MPEP 803, Rev. 8, May 1988) (emphasis added). The groups designated by the Examiner fail to define products with properties so distinct as to warrant separate examination and search. The present claims represent a web of knowledge and continuity of effort that merits examination in a single application.

Accordingly, Groups I-IV are related to method to reduce transcriptional interference using 4 specific spacer nucleotides, all of which are classified in class 435, subclass 455, as indicated by the Examiner. In addition, according to MPEP 803.04, "to further aid the biotechnology industry in protecting its intellectual property without creating an undue burden on the Office, the Commissioner has decided *sua sponte* to partially waive the requirements of 37 CFR 1.141 *et seq.* and permit a reasonable number of such nucleotide sequences to be claimed in a single application." Further

MPEP 803.04 states "...up to ten independent and distinct nucleotide sequences will be examined in a single application without restriction." Accordingly, the four sequences recited in claims 1-10 (Groups I-IV) should be examined by the Office without restriction.

Thus, all of these claims involve a fundamental determination of the novelty of a method to reduce transcriptional interference. To the extent that this determination would be made, it is submitted that a preponderantly coextensive search would result. In particular, an exhaustive search for a method to reduce transcriptional interference comprising SEQ ID NO: 1 of Group I would encompass the method to reduce transcriptional interference comprising SEQ ID NOs: 2, 3 or 4 of Groups II-IV, respectively. Performing an entire search covering the method to reduce transcriptional interference whether it is utilizing SEQ ID NO: 1, 2, 3 or 4 is less burdensome on the Examiner than separate searches, which necessarily involve duplication of searching efforts. Likewise with respect to Group V, performing the entire search covering the method to reduce transcriptional interference whether it is in a cell *in vitro* or in a cell *in vivo* is less burdensome on the Examiner than separate searches.

Thus, Applicants submit that the search and examination of the entire Application can be made without serious burden. Applicants respectfully submit that conjoint examination and inclusion of all of the claims of the present application would not present an undue burden on the Examiner, and accordingly, withdrawal of the Requirement for Restriction is believed to be in order.

Conclusion

Applicants respectfully submit that claims 1-14 are drawn to a single general inventive concept as defined in 37 CFR § 1.1. Thus, the inventions of Groups I-V as hereinabove defined, are not unrelated, and the search of the claims of these groups does not impose an undue search burden on the Examiner.

Applicants submit respectfully that the Examiner has provided insufficient reasons in support of a restriction between the inventions of Groups I-V. In view of the above remarks, Applicants respectfully request reconsideration and withdrawal of the finding of lack of relatedness between the claims of Groups I-V. All of the claims should fairly be examined in a single application. In the event that the restriction requirement is maintained, Applicants reserve the right to file divisional applications directed to the subject matter of the non-elected claims of Groups I, II, III and V. If a telephone

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interview would be of assistance in advancing prosecution of this application,
Applicants' agent invites the Examiner to contact her at (610) 650-8734 ext. 104.

Respectfully submitted,



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PTO/SB/17 (10-03)

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**FEE TRANSMITTAL
for FY 2004**

Effective 10/01/2003. Patent fees are subject to annual revision.

☒ Applicant claims small entity status. See 37 CFR 1.27**TOTAL AMOUNT OF PAYMENT** (\$) 475.00**Complete if Known**

Application Number	10/074,744
Filing Date	February 13, 2002
First Named Inventor	Padidam
Examiner Name	TA McKelvey
Art Unit	1636
Attorney Docket No.	A01183-US

METHOD OF PAYMENT (check all that apply)☐ Check ☐ Credit card ☐ Money Order ☐ Other ☐ None☒ Deposit Account:Deposit Account Number
Deposit Account Name

502860

RheoGene, Inc.

The Director is authorized to: (check all that apply)

☒ Charge fee(s) indicated below ☒ Credit any overpayments☒ Charge any additional fee(s) or any underpayment of fee(s)☐ Charge fee(s) indicated below, except for the filing fee to the above-identified deposit account.**FEE CALCULATION****1. BASIC FILING FEE**

Large Entity Fee Code (\$)	Small Entity Fee Code (\$)	Fee Description	Fee Paid
1001 770	2001 385	Utility filing fee	
1002 340	2002 170	Design filing fee	
1003 530	2003 265	Plant filing fee	
1004 770	2004 385	Reissue filing fee	
1005 160	2005 80	Provisional filing fee	
SUBTOTAL (1)			(\$)

2. EXTRA CLAIM FEES FOR UTILITY AND REISSUE

Total Claims	Extra Claims	Fee from below	Fee Paid
Independent Claims	-20** =	X	
Multiple Dependent	-3** =	X	

Large Entity Fee Code (\$)	Small Entity Fee Code (\$)	Fee Description
1202 18	2202 9	Claims in excess of 20
1201 86	2201 43	Independent claims in excess of 3
1203 290	2203 145	Multiple dependent claim, if not paid
1204 86	2204 43	** Reissue independent claims over original patent
1205 18	2205 9	** Reissue claims in excess of 20 and over original patent
SUBTOTAL (2)		

**for number previously paid, if greater; For Reissues, see above

FEE CALCULATION (continued)**3. ADDITIONAL FEES**

Large Entity Fee Code (\$)	Small Entity Fee Code (\$)	Fee Description	Fee Paid
1051 130	2051 65	Surcharge - late filing fee or oath	
1052 50	2052 25	Surcharge - late provisional filing fee or cover sheet	
1053 130	1053 130	Non-English specification	
1612 2,520	1812 2,520	For filing a request for <i>ex parte</i> reexamination	
1804 920*	1804 920*	Requesting publication of SIR prior to Examiner action	
1605 1,840*	1805 1,840*	Requesting publication of SIR after Examiner action	
1251 110	2251 55	Extension for reply within first month	
1252 420	2252 210	Extension for reply within second month	
1253 950	2253 475	Extension for reply within third month	\$475.00
1254 1,480	2254 740	Extension for reply within fourth month	
1255 2,010	2255 1,005	Extension for reply within fifth month	
1401 330	2401 165	Notice of Appeal	
1402 330	2402 165	Filing a brief in support of an appeal	
1403 290	2403 145	Request for oral hearing	
1451 1,510	1451 1,510	Petition to institute a public use proceeding	
1452 110	2452 55	Petition to revive - unavoidable	
1453 1,330	2453 665	Petition to revive - unintentional	
1501 1,330	2501 665	Utility issue fee (or reissue)	
1502 480	2502 240	Design issue fee	
1503 640	2503 320	Plant issue fee	
1460 130	1460 130	Petitions to the Commissioner	
1807 50	1807 50	Processing fee under 37 CFR 1.17(q)	
1806 180	1806 180	Submission of Information Disclosure Stmt	
8021 40	8021 40	Recording each patent assignment per property (times number of properties)	
1809 770	2809 385	Filing a submission after final rejection (37 CFR 1.129(a))	
1810 770	2810 385	For each additional invention to be examined (37 CFR 1.129(b))	
1801 770	2801 385	Request for Continued Examination (RCE)	
1802 900	1802 900	Request for expedited examination of a design application	

Other fee (specify) _____

*Reduced by Basic Filing Fee Paid

SUBTOTAL (3) (\$) 475.00**SUBMITTED BY**

Name (Print/Type)	Camille Jolly-Tornetta	Registration No. (Attorney/Agent)	48,592	Telephone	610/650-8734
Signature	<i>Camille Jolly-Tornetta</i>	Date	January 6, 2004		

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